MORRIS, NICHOLS, ARSHT & TUNNELL LLP

1201 NORTH MARKET STREET
P.O. BOX 1347
WILMINGTON, DELAWARE 19899-1347

(302) 658-9200
(302) 658-3989 FAX

MEGAN E. DELLINGER
(302) 351-9366
mdellinger@mnat.com

July 1, 2020

The Honorable Leonard P. Stark
U.S. District Court for the
District of Delaware
844 North King Street
Wilmington, DE 19801

VIA ELECTRONIC FILING

Re: *H. Lundbeck A/S v. Apotex Inc. et al.*, C.A. No. 18-088 (LPS) (consolidated)

Dear Chief Judge Stark:

Pursuant to the Court's order during the June 26, 2020 teleconference (D.I. 815 at 20:16-21:2), the parties to the above-referenced action write to provide their competing proposals for the completion of expert discovery, along with brief arguments in support of their proposals. The parties also include their arguments for their positions with respect to Defendants' request for leave to serve an expert report responding to Dr. Peck's opinions (D.I. 815 at 27:7-15, 28:5-12).

In light of the continuation of trial date in this matter, the parties have tentatively agreed to an expert discovery deadline of September 25, 2020. Reply reports are currently due on July 24, 2020.

Time Limits for Completion of Expert Depositions

Plaintiffs' Proposal

- Dr. Myerson's deposition on validity issues will not last more than 7 hours;
- Each Defendant shall have a total of 7 hours to depose Dr. Myerson and either Dr. Morin or Dr. Gozzo, as applicable, on infringement issues;
    - In other words, if Plaintiffs submitted a testing report from Dr. Gozzo and an "Appendix" from Dr. Myerson for a particular Defendant, that Defendant will have a total of 7 hours to use to depose Dr. Gozzo and Dr. Myerson;
- Dr. MacMillan's deposition will be limited to 9 hours;
- Dr. Lepore's deposition will be limited to 9 hours;
- Dr. Rothschild's deposition will be limited to 14 hours;
- All other depositions will be limited to 7 hours.

Defendants' Proposal

- Dr. Myerson's deposition on common issues of infringement and validity will not last more than 7 hours;

- Each Defendant contesting infringement (nine defendants) shall have a maximum of 10 hours to depose Dr. Myerson and either Dr. Morin (five defendants) or Dr. Gozzo (three defendants) as applicable, on infringement issues provided that no expert will be deposed for greater than 7 of the 10 hours;
    - In other words, if Plaintiffs submitted a testing report from Dr. Gozzo and an "Appendix" from Dr. Myerson for a particular Defendant, that Defendant will have a total of 10 hours to use to depose Dr. Gozzo and Dr. Myerson with no deposition of either expert lasting more than 7 hours;
- All other depositions will be limited to 7 hours.

Plaintiffs' Argument in Support of Their Proposal

Plaintiffs have 11 experts; Defendants have 17. Defendants' proposal would allow Defendants much more time with Plaintiffs' experts and leave Plaintiffs insufficient time with some of Defendants' experts. Plaintiffs' proposal is designed to give Plaintiffs and Defendants a comparable amount of overall deposition time sufficient to cover all issues in the case.

Plaintiffs' Experts. Plaintiffs served one report from Dr. Myerson on infringement of the crystalline form patents, which has an Appendix for each Defendant that disputes infringement of those patents. Dr. Myerson relies on XRPD testing performed by either Dr. Gozzo or Dr. Morin. Dr. Myerson also submitted a validity report. Defendants submitted non-infringement reports, each from a different expert, and a joint invalidity report from yet another expert.[1] Plaintiffs' proposal gives Plaintiffs and Defendants the same amount of time on issues of validity and infringement of the crystalline form patents.[2] Each side will have 7 hours on validity. The Hobson's choice on infringement Defendants complain about below is the same Hobson's choice Plaintiffs will have to make: how many of their 7 hours to use asking about the testing evidence as opposed to other infringement evidence.

Defendants' only justification for seeking additional time is that, if these were separate cases, they would purportedly be entitled 7 hours each with Dr. Myerson and the relevant testing expert. But, this is a consolidated action, and Defendants have represented that they plan to work together on these depositions. The Federal Rules do not require excessive deposition time—particularly where Defendants will benefit from a collective effort.[3]

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[1] Only Sigmapharm served two non-infringement reports. Under Plaintiffs' proposal, in fairness, they would similarly have 7 total hours to depose both of Sigmapharm's non-infringement experts.

[2] In a similar situation (where XRPD testing of an expert was relied upon by Dr. Myerson), six Defendants were given a total of 16 hours with Dr. Myerson and 10 hours with the testing expert. *In re Fetzima*, Civil Action No. 2:17-CV-10230-ES-SCM, D.I. 301 (D.N.J. June 29, 2020).

[3] Defendants previously mis-judged the amount of time they would need for depositions. During fact discovery, Defendants asked the Court to order 10-hour depositions with each inventor. June 19, 2018 Hearing Tr. at 36:10-37:6; 46:3-6. Defendants took fewer than 4.5 hours on the record with 4 out of 9 witnesses, who travelled from Denmark, and never needed more than 7.5 hours on the record with any inventor. One deposition lasted less than 1 hour.

Defendants' Experts. Defendants refuse to allow for more than 7 hours with their physician expert, Dr. Rothschild, who opines on both validity and non-infringement (for each of 11 Defendants) on two patents from two different families (the '910 and '096 Patents). Under Defendants' logic, Plaintiffs would get 84 hours with Dr. Rothschild. But Defendants will not agree to the 14 hours Plaintiffs seek. Plaintiffs have two different witnesses opining on these patents (Dr. Clayton and Dr. McIntyre) so Defendants will have 14 hours of deposition time on these patents. But, Defendants have refused to make Dr. Rothschild available for a comparable amount of time.

Defendants' expert Dr. Lepore opines on validity of the compound patents and a process patent. Plaintiffs have asked for a total of 9 hours compared to the 14 hours Defendants will have for these issues on these patents. Defendants have refused to make Dr. Lepore available for more than 7 hours.

Defendants' Argument in Support of Their Proposal

Defendants' proposal seeks to balance the Defendants' need for sufficient time to depose three of Plaintiffs' experts (Drs. Myerson, Gozzo, and Morin) who served multiple infringement reports with opinions unique to Defendants contesting the issue with Plaintiffs' concern about the burdens of up to nine seven-hour infringement depositions for these experts. Defendants propose a single seven hour deposition on common invalidity and infringement issues for Dr. Myerson, which will avoid hours of potentially duplicative testimony. Defendants also propose that each of the nine defendants be permitted up to ten hours collectively (no more than seven hours per witness) to depose Dr. Myerson and Drs. Gozzo or Morin (if applicable) on issues unique to that Defendant. This is consistent with *Bristol-Myers Squibb v. Aurobindo*, No. 17-374 (LPS) wherein plaintiffs' polymorph and testing experts were provided for seven hours on invalidity issues and ten hours on the nested infringement reports. Other than these three experts, Defendants propose that all remaining experts be deposed for no more than seven hours.

Additional time with Drs. Myerson, Gozzo, and Morin is appropriate because these experts offer their infringement opinions in a set of nested reports framed by Dr. Myerson's forty-one page umbrella report on common issues related to the four polymorph patents. In this umbrella report, Dr. Myerson offers generalized infringement opinions directed to the nine Defendants. He then attaches appendices directed to each individual Defendant, which contain his separate, independent opinions regarding each Defendant's ANDA. For the majority of Defendants, Dr. Myerson's appendices also include a separate expert report from either Dr. Gozzo (three reports) or Dr. Morin (five) regarding testing of that Defendant's product, that Dr. Myerson separately opines on. In a separate lengthy report, Dr. Myerson has also offered opinions on validity of polymorph patents. Reply reports are forthcoming, but Defendants expect that Drs. Myerson, Gozzo, and Morin will submit further reports on infringement.

By contrast, Plaintiffs' proposals concerning Drs. Myerson, Gozzo, and Morin result in inefficiency and prejudice. Without common deposition time, Dr. Myerson is likely to be subjected to unnecessary duplicative questioning on his common infringement opinions. Similarly, the mere seven hours of infringement deposition time split between Dr. Myerson and Drs. Gozzo or Morin for each applicable Defendant results in a Hobson's choice wherein many Defendants must choose how

they will be prejudiced. Address only some of Dr. Myerson's infringement opinions and risk having no time left to examine the testing expert about the complicated infringement testing; or spend significant time with the testing expert and risk having no testimony elucidating the bases for Dr. Myerson's independent opinions.

Plaintiffs' proposal also artificially truncates or extends various experts' depositions in an effort to prejudice Defendants. Plaintiffs seek expanded time with Defendants' experts, Dr. Rothschild (fourteen hours) and Dr. Lepore (nine hours) simply because each expert offered opinions on multiple patents where Plaintiffs chose to address these same patents with highly duplicative testimony from multiple experts. Plaintiffs' litigation strategy that results in more experts being deposed on their side on the same subject matter does not justify Defendants' experts being subjected to increased deposition burdens, especially when all experts opining on the method of treatment claim utilized a single, "representative" label, including Dr. Rothschild.

Defendants' Request for Leave to Serve an Expert Report Responding to Dr. Peck

Defendants' Argument in Support

As discussed during the June 26, 2020 telephone conference, Defendants request leave to file an expert report in response to Plaintiffs' FDA expert, Dr. Peck. Rule 37 provides that "[i]f a party fails to provide information or identify a witness [in the manner required by the Court under Rule 26], the party is not allowed to use that information or witness . . . at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(l). Here, allowing Defendants to serve a responsive FDA expert report is both justified and harmless.

A responsive FDA expert report is justified because in denying Defendants' motion to strike Dr. Peck's report, the Court concluded that "it will find [Dr. Peck's] testimony . . . helpful to it in its role as factfinder." (D.I. 801.) Defendants believe that it would be helpful for the Court to hear not just from Dr. Peck but also Defendants' FDA expert so that the Court can render its decision on a complete record. Defendants were justified in not serving a responsive FDA expert report sooner because the very purpose of Defendants' motion to strike was "to prevent the unnecessary expenditure of resources . . . ." (D.I. 768 at 1). Serving a responsive FDA expert report would have defeated that purpose.

Granting leave to submit a responsive report to Dr. Peck is also harmless. There is ample time to complete FDA expert discovery by the proposed cut-off for expert discovery (September 25, 2020). This provides the parties with three months to exchange rebuttal and reply reports and depose the FDA experts.[4] Defendants propose that their FDA expert report be due two-weeks from the date that Plaintiffs approve Defendants' expert under the Protective Order (Plaintiffs marked the Peck report "Confidential"), and Plaintiffs may take as much time as they like to serve a reply report so long as it is served two weeks prior to Dr. Peck's deposition.

[44] Courts have found that sufficient time to depose an expert who serves an untimely report militates in favor of allowing the expert's testimony. *See*, *e.g.*, *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, No. C.A. 04-1371-JJF, 2006 WL 2435083, at *1 (D. Del. Aug. 22, 2006).

This framework allows the Court to receive FDA expert testimony from both sides while eliminating any prejudice to Plaintiffs. The absence of prejudice to Plaintiffs is confirmed by the fact that Plaintiffs originally consented to Defendants' request to serve a rebuttal FDA expert report so long as Defendants agreed to Plaintiffs' deposition time limits. This reveals that Plaintiffs' opposition is grounded in negotiating tactics, rather than a legitimate claim of prejudice.

Plaintiffs' Argument in Opposition

Defendants waited 5 weeks, until 9 days before rebuttal reports were due, to move to strike Dr. Peck's report. And they then requested only that the Peck report be stricken—they did not request leave to file a late rebuttal report if their motion was denied. D.I. 767. They simply chose not to serve a rebuttal report by the deadline, despite the risk that the Court would deny their motion. Defendants' request should be denied because (1) it comes too late and (2) Defendants cannot show "good cause" to modify the Scheduling Order to permit them to serve a late rebuttal report. As to timing, Defendants waited until after they had already lost to request alternative relief. Defendants' request should be denied on that basis alone. *See, e.g.*, *Watkins v. Int'l Union*, C.A. No. 15-444-LPS, 2016 WL 1166323, at *4 n.4 (D. Del. Mar. 23, 1016) ("Because this argument was made for the first time at the hearing, the Court will not consider it.").

Defendants also cannot show the "good cause" required under Rule 16(b)(4) to modify the Scheduling Order. "Good cause is present when the schedule cannot be met despite the moving party's diligence." *Meda Pharms. Inc. v. Teva Pharms. USA, Inc.*, C.A. No. 15-785-LPS, 2016 WL 6693113, at *1 (D. Del. Nov. 14, 2016). There is no reason why Defendants could not have timely served an expert report or at least have sought relief in advance. They simply chose not to, in the hope that the Court would grant their motion to strike and they would not have to undertake the expense to prepare a report.[5] "A strategic mistake does not equate to a showing of good cause under Rule 16." *St. Clair Intellectual Prop. Consultants, Inc. v. Matshushita Elec. Indus. Co.*, C.A. No. 04-1436-LPS, 2012 WL 1015993, at *6 (D. Del. Mar. 26, 2012).

Defendants' decision to proceed this way also prejudices Plaintiffs. First, Plaintiffs had to respond to Defendants' motion while preparing their rebuttal expert reports. Now, Defendants' request would require Plaintiffs to prepare another reply report while also preparing for and taking 27 other expert depositions. Plaintiffs should not have to pay the price for Defendant's strategic decision.

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Counsel for the parties are available at Your Honor's convenience should the Court have any questions.

[5] Besides expense, Defendants cited the fact that Plaintiffs' motion to amend was pending and the Peck report briefly addressed inducement as a basis for not preparing a rebuttal. But Defendants were willing to address inducement in another of their expert reports, despite that uncertainty.

Respectfully,

/s/ Megan E. Dellinger

Megan E. Dellinger (#5739)

MED/bac

cc: All Counsel of Record (via electronic mail)